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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,473	01/21/2004	John C. Rueter	P0011409.00	4388

27581 7590 10/14/2009
MEDTRONIC, INC.
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EXAMINER

GEDEON, BRIAN T

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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10/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/761,473	Applicant(s) RUETER, JOHN C.	
	Examiner Brian T. Gedeon	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. This action is in response to the amendment after non-final filed 1 July 2009.
Claims 1-24 are pending.

Response to Arguments

2. Applicant's arguments, see Remarks, filed with respect to the rejection(s) of claim(s) 1-24 under Levine et al. (US Patent no. 7,308,310) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Jorgenson et al. (US Patent no. 6,317,633).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Upon review and reconsideration of the claims, claims 1-24 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

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invention. The subject matter added, particularly to claims 1, 11, 12, and 22, in the previous amendment dated 13 August 2008 further limiting the "absence of a pacing threshold search that comprises delivering pacing pulses" cannot be found described in the specification.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is indefinite if the "delivering of pacing pulses" in claims 1, 11, 12, and 22 comprises the step of monitoring for indicator or if it comprises part of the pacing threshold search that is absent.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-6, 11-16, 21, and 22 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Jorgenson et al. (US Patent no. 6,317,633) in view of Schloss (US Patent no. 6,456,882).

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In regard to claims 1, 11, 12, and 22, Jorgenson et al. describe an implantable pulse generator (IPG) 26 sealed in housing 18, col 7 lines 49-59. Electrodes 20 and 22 are carried on lead 16 and electrodes 28 and 30 are carried on lead 14, and are coupled to the IPG to deliver electrical stimulus pulses to cardiac tissue, col 7 line 60 - col 8 lines 13. A microcomputer 302 contains a microprocessor 304 to control the operational functions of the IPG, col 10 lines 66-67 and col 11 lines 33-35. A lead impedance test circuit 342 conducts a lead status monitoring (LSM) test to process information regarding the function of the implantable leads by measuring the impedance of a lead, col 5 lines 57-60, 64-65, col 6 lines 23-26, col 9 lines 6-23, and col 13 lines 44-46. Jorgenson et al. are concerned with lead status, based on impedance, because lead breakage impedes sensing conditions causing cardiac signals to be attenuated or distorted. Lead status also affects cardiac pacing procedures because increase impedance in the path of pacing signal reduces the effective pacing pulse energy, thereby resulting in loss of capture, col 3 lines 1-23. When loss of capture occurs, it is known that the threshold energy required to achieve capture is increased. Therefore, in view of this teaching, it is considered that increased lead impedance is an indicator of a likely increase in threshold required to effectively capture the heart. Jorgenson et al. also teach that it is well known in the art to provide a safety margin between the actual delivered pacing pulse, however do not teach that the safety margin is increased in response to perceived increase in the pacing threshold. Jorgenson et al. though teach that the amount of the safety margin may change over time, col 13 lines 19-23.

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Schloss describes an implantable medical device 700 comprising: a pulse generator 80, for delivering pacing pulses; at least one electrode 75 and 77, in electrical communication with the pulse generator for delivering the pacing pulses to cardiac tissue; and a microprocessor 22 for controlling the pulse generator, receiving sensed data from the at least one electrode, wherein the sensed data includes an indicator, col 12 lines 27-30, of increased pacing threshold, and increasing a safety factor, col 12 lines 25-27, used for setting the pacing pulse energy delivered by the pulse generator when the indicator of increased pacing threshold is detected, also see figure 3. Schloss also teaches that in a variation of the invention the safety margin is immediately increased for the stimulation pulse such that the necessity for a threshold search to be performed, col 12 lines 35-38.

Therefore it is considered obvious to one of ordinary skill in the art at the time the invention was made to modify Jorgenson et al. to increase a pacing safety margin for a pacing pulse in response to a detected indicator of pacing threshold since Schloss provides teaching that increasing a safety margin in such a manner is known in the art.

In regard to claims 2-5 and 13-15, Schloss teaches setting a time interval during which the increased safety factor is maintained; and restoring the safety factor to a programmed value after the time interval has expired, col 3 lines 42-47, and setting a time interval during which the increased safety factor is maintained; and restoring the safety factor to a programmed value after the time interval has expired, col 3 lines 37-41. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Levine et al. with the teaching of

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Schloss in order to determine if the safety margin adjustment criteria has been met, and that excess energy is not expended if deemed not necessary by having a high safety margin.

In regard to claims 6, 16, and 21, Jorgenson et al. teach that a threshold increase indicator may be associated with lead impedance, col 3 lines 1-23

9. Claims 7-10 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgenson et al. (US Patent no. 6,317,633) in view of Schloss (US Patent no. 6,456,882), further in view of Sloman et al. (EP 1 136 098 A2 – provided on Applicant's IDS dated 5/12/2005).

In regard to claims 7-10 and 17-20, Jorgenson et al. in view of Schloss substantially describe the invention as claimed except for the indicators of increased pacing threshold. Sloman et al. describes an implantable medical device 10 comprising: a pulse generator 70 and 72, col 7 lines 40-45, for delivering pacing pulses; at least one electrode 26, 27, and 28, see fig. 1 and col 6 lines 5-8, in electrical communication with the pulse generator for delivering the pacing pulses to cardiac tissue; and a microprocessor 60, col 7 lines 17-18, for controlling the pulse generator, receiving sensed data from the at least one electrode, wherein the sensed data includes an indicator, col 17 line 28, of increased pacing threshold, and increasing a safety factor, col 17 lines 19-22, used for setting the pacing pulse energy delivered by the pulse generator when the indicator of increased pacing threshold is detected. Sloman et al. have an impedance sensor 112, an arrhythmia detector, col 11 lines 25-47, a

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refractory period detector, col 8 lines 1-2, and/or change in pacing/stimulation modes, col 12 lines 4-15. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Jorgenson et al. in view of Schloss. with the teachings of Sloman et al. since Sloman et al. discloses means and methods for detecting various indicators indicating an increased threshold.

Conclusion

10. In view of the new ground of rejection, this action is made **NON-FINAL**.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

Carl H. Layno
Examiner
Art Unit 3766

/B. T. G./
Examiner, Art Unit 3766
10 October 2009